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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,438	11/13/2001	Bernard A. Hausen	032405-059 US	7508

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CARDICA, INC.
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EXAMINER

ROBERTS, PAUL A

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,438

Applicant(s)

HAUSEN ET AL.

Examiner

Paul A Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/13/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 9, 19-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a method of performing anastomosis, classified in class 606, subclass 153.
- II. Claims 20-30, drawn to a tool for performing anastomosis, classified in class 606, subclass 185.
- III. Claim 31-44, drawn to an integrated stabilizer, classified in class 606, subclass 1.

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods do not require the apparatus as claimed. The method of group I could be applied to the device of US 5702412.

Inventions II and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention III has separate utility such as stabilizing any skeletal muscle that might require suturing. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant has disclosed and claimed two approaches for the surgery: a sub-xyphoid approach and an intercoastal approach.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-7 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Brian Shar on May 15, 2003 a provisional election was made without traverse to prosecute the invention of the sub-xyphoid approach, claims 1-8 & 10-18. Affirmation of this election must be made by applicant in replying to this Office action.

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Claims 9 and 19-44 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-2, 7, and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sterman et al. US 5735290. In figure 3, Sterman shows a closed chest approach to coronary bypass surgery. In col. 14, 17-30 Sterman discloses that any conventional technique may be applied to connect the graft to the vessel. He specifically lists stapling. Figures 9-13 show the graft being attached. Tool 96 would go through one of the chest openings. Figure 8 shows the step of opening the target vessel. The grasper of Sterman splits to release the vessel. A grasper as shown in figure 3, inherently opens the blades (splits) to release the object the blades are holding.

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2. Regarding claim 11, Sterman discloses the ports shown in figure 3 are called trocar sheaths.
3. Regarding claims 12 and 13, Sterman discloses in col. 13, lines 18-28 that the step of creating a hole in the pericardium is required to allow the instruments access to the innards of the heart.
4. Regarding claim 14, a clamp is shown in figure 8 as item 102.
5. Regarding claim 15, the graft vessel, shown as element 101, is sliced in figure ..
6. Regarding claim 16, the clamp tool shown in figure 8 is connected to the tool 32 in figure 3. The handle of the clamp assembly is considered the tool that is attached to the clamp.
7. Regarding claim 17, the anastomosis site is viewed through a scope as described in col. 6 lines 54-60.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. US 5735290 in view of Wolf et al. US 6066144. Sterman discloses all of claims 1-2 as discussed above. Sterman also discloses the step of tensioning the target vessel by a grasping member 102, in figure 8. The grasper of Sterman splits to release the vessel. A grasper as shown in figure 3, inherently opens the blades (splits) to release the object the blades are holding. Tool 102 of

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Sterman is deployed substantially normal to vessel. Sterman does not explain in detail the method of stapling. The Wolf endoluminal stapler is disclosed to be used for anastomosis. Col 10, 25-60 details the method of use of the device which includes stapling a graft vessel to the target vessel, inserting an anvil through the wall of the target vessel into the lumen of the target vessel, and moving the anvil against the side of the target vessel. The stapler of Wolf deploys the anastomosis device (the staple) to the target vessel. The Wolf device is especially designed to minimize trauma associated with manipulating blood vessels (col. 4, 5-15). At the time of the invention it would have been obvious to one of ordinary skill in the art to use the Wolf stapler with the Sterman bypass apparatus because stapling is a known anastomosis technique and the Wolf stapler provides a method and apparatus to minimize manipulation of the blood vessels.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. US 5735290 in view of Popov et al. US 5702412. The Sterman device discloses all of claim 1 but does not disclose the use of a sub-xyphoid approach. Rather, the Sterman device uses an intercoastal approach. However, both closed chest surgical methods are well known in the art. Popov describes that a sub-xyphoid approach is preferred for use in closed chest surgery. In col. 2, lines 32-39, Popov discloses that the use of a sub-xyphoid approach helps alleviate the trauma associated with non-percutaneous heart bypass surgery. At the time of the invention it would have been obvious to one of ordinary skill in the art to use the Popov sub-xyphoid approach with the Sterman method because the Popov approach helps reduce the healing time of the patient by providing a minimally invasive method to allow a CABG.

10. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. US 5735290 in view of Berg et al. US 6475222. Sterman discloses all of claim 1, but does

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10. Claims 1 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sterman et al. US 5735290 in view of Berg et al. US 6475222. Sterman discloses all of claim 1, but does not disclose the necessary step of measuring the vein in the anastomosis site by using a tool that is inserted through the thoracic cavity. This step is necessary (but not disclosed by Sterman) because one could not simply guess the length of the graft to place into the body. The graft must span the distance of the anastomosis site exactly. Additionally the step of measuring the length of the graft with a vein measuring device is explicitly taught by Berg in col. 11, lines 20-23. At the time of the invention it would have been to one of ordinary skill in the art to use the vein measuring device of Berg to measure the length of the graft to be anastomosed in the Sterman method because it is necessary to measure this distance to ensure the correct length of graft vessel will be placed into the body.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5452733 A	Methods for performing thoracoscopic coronary artery bypass
US 5433700 A	Method for intraluminally inducing cardioplegic arrest and catheter for use therein
US 5250038 A	Multiple lumen vascular access introducer sheath
US 5203776 A	Catheter for heart surgery
US 5104393 A	Catheter for heart surgery

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
June 12, 2003


MICHAEL J. MILANO 4/12
SUPERVISORY PATENT EXAMINER
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